AUG 1 0 2000

K00/609

SECTION 2 - Summary and Certification

COMPANY INFORMATION

Mallard Medical, Inc.
20268 Skypark Drive
Redding, California 96002
530 226 0727 Ph. 530 226 0713 Fax.
contact: Robert M. Pearson, President

PREPARATION DATE OF SUMMARY

16 May 2000

TRADE NAME

Mallard Air Oxygen accuBlender

COMMON NAME

Mixer, Breathing Gases, Anesthesia Inhalation

PRODUCT CLASSIFICATION

Class II, per 868.5330 Product Code: 73 BZR

PREDICATE DEVICES

K992503 Sechrist Air-Oxygen Mixer
K925982 Bio-Med Devices Air/Oxygen Blender
K883038 Bird Products Low Flow Air/Oxygen Blender
K802226 Sechrist Air-Oxygen Mixer

DESCRIPTION

The Mallard Air Oxygen accuBlender is a device which mixes medical grade compressed air and oxygen to provide a selectable gas mixture of 21% to 100% oxygen. The accuBlender is designed to use 50 PSIG gas sources such as those commonly found in hospitals. The gas source pressures are balanced within the accuBlender by a nulling regulator. The balanced gas pressures are then proportioned by a double needle valve arrangement positioned by a calibrated control knob. The mixed gas outlet flow is typically controlled by a standard flowmeter. The accuBlender is designed for a flow range of 1 to 15 Liters per Minute. An alarm/bypass system is incorporated which allows the higher gas pressure source to be delivered to the outlet should one of the source gases fail, simultaneously activating an audible tone.

INDICATIONS FOR USE

The Mallard Air Oxygen accuBlender is designed to provide a continuous flow air/oxygen gas mixture to infant, pediatric and adult patients. It is a restricted medical device intended for use by qualified, trained personel under the direction of a physician in institutional environments where the delivery of controlled air/oxygen mixtures is needed. It is also intended for use as an OEM component of various devices which require a selectable air/oxygen gas mixture to be delivered to a patient, such as ventilators, infant and adult nasal cpap devices and cardio-pulmonary bypass systems.

CONTRAINDICATIONS, PRECAUTIONS and WARNINGS

There are no known contraindications for this device.

TECHNICAL CHARACTERISTICS

Nominal Supply Pressure	50+/-10 psig
Media	Medical Grade Air and Oxygen
Operating Pressure Capability	30 to 70 psig
Flow Range	1 to 15 lpm
% O2 Control	21% to 100% +/-3%

NON-CLINICAL DATA

The accuBlender was tested to conform to the design requirements and compared to the performance of substantially equivalent devices. The The test report summary is included in Appendix E and a product comparison matrix is included in Section 5.

CONCLUSION

The testing performed and comparison to predicate devices demonstrate that the proposed device is safe and effective and is substantially equivalent to predicate devices.

Signatures

A. Edwin Weninger
Vice President Product Development
& Quality Assurance

Robert M. Pearson
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2000

Mr. Robert Pearson
Mallard Medical, Inc.
20268 Skypark Drive
Redding, CA 96002

Re: K001609
Mallard Air Oxygen Accublender
Product Code: 73 BZR
Dated: May 16, 2000
Received: May 24, 2000

Dear Mr. Pearson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K0001609

Device name accuBlender

Indications For Use:

The Mallard Air Oxygen accuBlender is intended to provide a controllable air/oxygen gas mixture to patients through various types of respiratory care equipment. It is a restricted medical device intended for use by qualified, trained personal under the direction of a physician in institutional environments where the delivery of controlled air/oxygen mixtures is needed. Federal Law restricts this device to sale by or on the order of a Physician.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Division of Cardiovascular & Respiratory Devices
510(k) Number K001609

X PRESCRIPTION USE _ OVER-THE-COUNTER